



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Rahal, James

Examiner: Winkler, Ulrike

Serial No.: 09/935,966

Group Art Unit: 1648

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Docket No.: 13099

For: Methods of Preventing or Treating West Nile Virus and Other Infections

Customer No.: **23719**

Kalow & Springut LLP
488 Madison Avenue, 19th Floor
New York, NY 10022

February 2, 2005

Commissioner for Patents
P.O. Box 1450
Alexandria, VA. 22313-1450

DECLARATION OF DR. JAMES J. RAHAL

I, Dr. James J. Rahal, hereby declare that:

1. I am the inventor of the above-identified application.
2. I received my A.B in Biology from Harvard College in 1955 and my M.D. degree from Tufts University School of Medicine in 1959. I have worked extensively since at least as early as 1963 in the Infectious Diseases field. I have authored numerous publications including textbook chapters in the Infectious Diseases field. Since 1988, I have been Director of the Infectious Disease Section at The New York Hospital Medical Center of Queens. I am also Professor of Medicine and Assistant Dean at Weill College of Medicine, Cornell University. A copy of my curriculum vitae is attached.

3. I submit this declaration based upon: (i) my training, knowledge, education, and experience in the Infectious Diseases field; (ii) my review of the above-referenced application and the history of the prosecution of this application; and (iii) the clinical trial conducted which shows that interferon alpha-2b treatment for West Nile Virus meningo-encephalitis, an infection causing the combination of meningitis and encephalitis, resulted in significantly improved neurological functional status, a sign that the infection is resolving.
5. I disagree with the Examiner's opinion that there is lack of enablement for the administration of interferon alpha-2b via the parenteral route for the treatment of West Nile Viral (WNV) meningitis, encephalitis, or meningo-encephalitis discussed in the June 4, 2004 Final Office Action at page 6.
6. In order to assess whether interferon alpha-2b was effective for the treatment of WNV meningo-encephalitis, a randomized, unblinded, multi-institutional clinical study was conducted using the protocol I developed and that is described in Example 3 of the specification at pages 14-16. The dose and route of administration of interferon alpha-2b was 3 million units intravenously (IV) initially; then 3 million units subcutaneously 12 hours later, then 3 million units subcutaneously every 24 hours for up to 14 days of therapy (as described on page 15, lines 14-20 of the specification).
7. The clinical study methods were as follows:
 - a) Patient Enrollment:

During the summers of 2002-2003, patients with clinical and epidemiologic evidence of WNV meningo-encephalitis were enrolled. Patients were randomly assigned into two groups: group 1 received interferon alpha-2b for two weeks (6 million units initially-3 million units intravenously (IV) initially; then 3 million units subcutaneously 12 hours later) followed by 3 million units daily plus standard supportive therapy; group 2 did not receive interferon, but received standard supportive therapy alone. Treatment was initiated prior to the results of WNV serologic studies. Patients with serologically-proven WNV infection and follow-up examination after 3 weeks were included in the outcome analysis.
 - b) Interferon Dose Regimen

IV interferon alpha-2b was given at a dose of 3 million units initially; then 3 million units by subcutaneous injection 12 hours later, followed by 3 million units subcutaneously every 24 hours to complete up to 14 days of therapy if tolerated. The interferon alpha-2b in the clinical study was given by the intravenous and subcutaneous route and **not** by intracranial administration.

c) Clinical Evaluation of Outcome:

19 patients were randomized to each group. Among the interferon treated patients, 2 were seronegative, 1 was lost to follow up, and 1 died within the first 36 hours. Among the patients that did not receive interferon, 4 patients were seronegative, 4 were lost to follow up, and three withdrew. Thus, 15 interferon treated and 8 patients that did not receive interferon were eligible for analysis. The evaluation of outcome was determined by assessment of neurologic status at enrollment, using the National Institute of Health Stroke Scale (N.I.H.S.S.), which provides an initial functional score of 0 or negative number (lowest function) to 42 (highest function). The neurologic examination is scored with the N.I.H.S.S. to quantify the degree of neurologic dysfunction from the WNV infection. Neurologic dysfunction is the result of active viral invasion of the CNS causing inflammation and ultimate cell destruction. Resolution of neurologic dysfunction is a sign of resolving infection. A high N.I.H.S.S. score correlates with a large neurologic dysfunction. In the clinical study, this scale was used to assess whether CNS infection, such as a meningitis or encephalitis, is resolving. Subsequent examinations help quantify the progress of the patient. Typically, the patient is assessed and scored as follows:

Level of Consciousness

- 0 = Alert, keenly responsive
- 1 = Drowsy, arousable by minor stimulation to obey, answer, or respond
- 2 = Responds only with reflex motor or autonomic effects, or totally unresponsive

Level of Consciousness Question: Patients are asked the month and their age

- 0 = Both correct or language barrier
- 1 = One correct
- 2 = Both incorrect, or unable to respond

Level of Consciousness Command: The patient is asked to close the eye and the hand

- 0 = Both correct or language barrier
- 1 = One correct
- 2 = Both incorrect, or unable to respond

Best Visual: Test vision in each field to finger movement simultaneously

- 0 = Normal or old blindness
- 1 = Asymmetry or partial hemianopia
- 2 = Complete hemianopia
- 3 = Bilateral hemianopia or coma

Best Gaze

- 0 = Full range of eye movements
- 1 = Partial gaze palsy or isolated nerve palsy
- 2 = Forced deviation or total gaze paresis not overcome by Doll's eye maneuver

Facial weakness

- 0 = None or sedated
- 1 = minor (just loss of naso-labial fold)
- 2 = Partial (lower half of the face)
- 3 = Complete (all half involved) or coma

Best Motor Left Arm: The patient holds the arm outstretched at 90 degrees.

- 0 = Limb holds 90 degrees for full 10 seconds, effusion or amputation
- 1 = Limb holds 90-degree position, but drifts before full 10 seconds
- 2 = Limb cannot hold 90-degree position for full 10 seconds, some effort against gravity
- 3 = Limb falls, no effort against gravity
- 4 = No movement

Best Motor Right Arm: The patient holds the arm outstretched at 90 degrees.

- 0 = Limb holds 90 degrees for full 10 seconds, effusion or amputation
- 1 = Limb holds 90-degree position, but drifts before full 10 seconds
- 2 = Limb cannot hold 90-degree position for full 10 seconds, some effort against gravity
- 3 = Limb falls, no effort against gravity
- 4 = No movement

Best Motor Left Leg: The patient elevates the leg at 30 degrees for 5 seconds.

- 0 = Leg holds 30-degree position for 5 seconds, effusion or amputation
- 1 = Leg falls to intermediate position by end of 5 seconds
- 2 = Leg falls to bed by 5 seconds, some effort against gravity
- 3 = Leg falls to bed immediately, no resistance against gravity
- 4 = No movement

Best Motor Right Leg: The patient elevates the leg at 30 degrees for 5 seconds.

- 0 = Leg holds 30-degree position for 5 seconds, effusion or amputation
- 1 = Leg falls to intermediate position by end of 5 seconds
- 2 = Leg falls to bed by 5 seconds, some effort against gravity

- 3 = Leg falls to bed immediately, no resistance against gravity
- 4 = No movement

Limb Ataxia: Finger-to-nose and heel-to-shin test

0 = Absent (no movement of limb), can not be examined

1 = Ataxia present in one limb

2 = Ataxia present in two limbs

Sensory: Pin prick. If level of consciousness is impaired, score only if a grimace or asymmetric withdrawal is present.

0 = Normal, sedated or amputation

1 = Mild to moderate. Patient feels pin prick less sharp, but is aware of being touched

2 = Severe to total sensation loss, not aware of being touched

Neglect

0 = No neglect or sedated

1 = Visual, tactile, or auditory hemi-inattention

2 = Profound hemi-inattention to more than one modality

Dysarthria

0 = Normal

1 = Mild to moderate slurring of words, can be understood

2 = Speech slurred, unintelligible

Best Language: Standard pictures are named.

0 = Normal

1 = Mild to moderate naming errors, word-finding errors, or paraphasias.

Impairment of communication by either comprehension or expression.

2 = Severe: fully developed Broca's (expressive) or Wernicke's (receptive) aphasia

3 = Mute or global aphasia or coma.

The N.I.H.S.S. in this trial was determined again at 1, 2, and 3 weeks after enrollment. The difference between the functional score at enrollment and after 3 weeks was determined for each group. The effectiveness of interferon alpha-2b was determined by a comparison of the mean change in N.I.H.S.S. scores among interferon treated patients and patients that did not receive interferon.

d) **Results:**

The change in N.I.H.S.S. for the interferon treated patients at 3 weeks after enrollment is shown in Table 1 and untreated patients is shown in Table 2.

Table 1
Neurological Score After 3 Weeks For Patients Given Interferon

Patient No.	Neurological Score (0 to +23)	Interferon Dose And Length Of Treatment	Age (M/F)	Serum +/-
1	+5	14	74 M	+
2	0	14	53 M	+
3	+6	10	81 F	+
4	+7	12	81 M	+
5	+5	14	40 M	+
6	+20	14	73 F	+
7	+20	14	75 M	+
8	+6	10	83 F	+
9	+2	14	45 M	+
10	+8	10	76 F	+
11	+12	14	47 M	+
12	+23	14	85 F	+
13	+7	14	66 M	+
14	+12	14	25 M	+
15	+11	14	73 M	+
Mean	+9.6 (p=.008)	13.1	Age 65.1	All positive

Table 2
Neurological Score After 3 Weeks For Patients Not Given Interferon

Patient No.	Score (-1 to +8)	Age (M/F)	Serum +/-
1	+6	74 M	+
2	+2	65 F	+
3	+3	68 M	+
4	+1	57 F	+
5	+1	71 M	+
6	+4	80 M	+
7	-1	62 M	+
8	+8	62 M	+
Mean	+3.0 (p=.008)	Age 67.4	All positive

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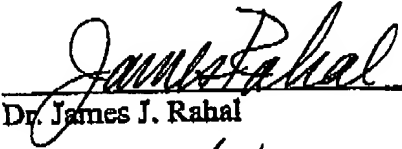

Changes designated with a plus sign indicate the degree of improvement, and by a minus sign indicate the degree of deterioration, on a scale of 0-42. The mean improvement among 15 treated patients was +9.6 and among 8 untreated patients, +3.0. This difference is statistically significant ($p = 0.008$ by 2-tailed Fisher's randomization test) with a confidence of greater than 95%. Alpha-2b interferon was given for an average of 13.1 days. The most common adverse events were elevation of serum transaminase and neutropenia. Grade 3 hepatotoxicity occurred in 37.5% of the patients, and grade 3 neutropenia in 31% of the patients. These events resolved with drug cessation.

e) Conclusion:

Treatment of patients with West Nile viral meningitis or encephalitis with interferon alpha-2b by the IV route for up to 14 days results in a significantly improved neurologic functional status and survival after three weeks, as compared to patients that did not receive the interferon alpha-2b.

8. Thus, following my protocol described in Example 3 of the specification, for example page 15, lines 14-20, one of ordinary skill in the art can use interferon alpha-2b IV, initially, followed by subcutaneous injections for the successful treatment of WNV meningo-encephalitis. Again, the interferon alpha-2b is not administered by the intracranial route, but by the IV route at a dose of 3 million units IV initially; then 3 million units subcutaneously 12 hours later, then followed by 3 million units subcutaneously every 24 hours for up to 14 days of therapy. Accordingly, the specification clearly enables this treatment and the clinical trial further supports this treatment protocol.

9. All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true. All statements are made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.


Dr. James J. Rahal

Date



CURRICULUM VITAE

NAME: James J. Rahal, Jr.
BORN: Boston, Massachusetts; October 14, 1933
EDUCATION: Harvard College, A.B. cum laude, 1955
Tufts University School of Medicine, M.D.
cum laude. Alpha Omega Alpha, 1959

POSTGRADUATE TRAINING:

Intern and Assistant Resident in Medicine
Second (Cornell) Medical Division
Bellevue Hospital, New York, N.Y. - 1959-1961.

Senior Resident in Medicine
New England Medical Center Hospitals - 1961-1962.

Chief Resident In Infectious Diseases
New England Medical Center Hospitals - 1963-1964

U.S.P.H.S Trainee in Infectious Diseases - New England
Medical Center Hospitals - 1962-1963; 1964-1965.

FULL TIME APPOINTMENTS:

Assistant Physician, Department of Medicine and
Infectious Disease Service, New England Medical
Center Hospitals 1965-1969.

Instructor in Medicine, Tufts University School
of Medicine 1965-1966.

Senior Instructor in Medicine, Tufts University
School of Medicine - 1966-1968.

Assistant Professor of Medicine, Tufts University
School of Medicine - 1968-1969

Assistant Professor of Medicine, New York University
School of Medicine - 1969-1974.

Chief, Division of Infectious Disease, Manhattan
Veterans Administration Medical Center - 1969-1986.

Chief, Infectious Disease Section, New York Infirmary
Beekman Downtown Hospital 1986-1988.

Associate Professor of Medicine, New York University
School of Medicine - 1974-1989.

Director, Infectious Disease Section, The New York Hospital Medical Center of Queens, formerly Booth Memorial Medical Center - 1988-present.

Associate Professor of Medicine, Albert Einstein College of Medicine - 1988-1991.

Visiting Professor of Medicine, Albert Einstein College of Medicine - 1994-present.

Professor of Medicine, Albert Einstein College of Medicine - 1991-1992.

Clinical Professor of Medicine, Weill College of Medicine, Cornell University - 1992-2000.

Professor of Medicine, Weill College of Medicine, Cornell University - 2001-present.

Assistant Dean, Weill College of Medicine, Cornell University - 2004-Present

Director, Certified Infectious Disease Training Programs:

New York (Manhattan) V.A. Medical Center 1970-1986

New York Hospital Medical Center of Queens 1988-present

SPECIALTY BOARDS:

American Board of Internal Medicine - 1967

American Board of Infectious Diseases - 1972

RESEARCH AWARDS:

Research Fellowship - Medical Foundation of Boston - 1966-1968

Principal Investigator - USPHS Research Grant #AI-07066

"Mechanism of Action of Bacterial Exotoxins" 1966-1969

Principal Investigator - Veterans Administration Research Grant - "Biochemical Mechanisms in Septic Shock: The Role of Bacterial Toxins" 1971-1978

Chairman - V.A. Cooperative Study #89 - "Nafcillin Therapy of Staphylococcal Bacteremia: Four week versus six week therapy for staphylococcal endocarditis and two week versus four week therapy for bacteremia without evidence of endocarditis" - 1978-1981

Albion O. Bernstein, MD Award - April 17, 2004 - Presented by the Medical Society of the State of New York in recognition of identification, treatment and prevention of nosocomial infection with multi-drug resistant gram negative organisms.

TEACHING AWARDS:

Teacher of the year Award-Booth Memorial Medical Center Medical Housestaff - 1988-1989

First Annual Infectious Disease Fellows Award-Albert Einstein College of Medicine - 1991-1992

RESEARCH APPOINTMENT:

Visiting Investigator, Department of Biochemistry, Public Health Research Institute of the City of New York, 1969-1970

SCIENTIFIC SOCIETIES:

Fellow-Infectious Diseases Society of America

President, New York Society of Infectious Diseases 1996-97.

Fellow-American College of Physicians

American Federation for Clinical Research

American Society for Microbiology

American Association for the Advancement of Science

PROFESSIONAL COMMITTEES - REGIONAL AND NATIONAL:

Advisory Expert Committee on Infectious Disease Control - New York City Department of Health, Member, 1974-1985

Veterans Administration Advisory Committee on Infectious Disease, V.A. Central Office, Washington, D.C., Member, 1976-1981

New York State AIDS Institute - Subcommittee on Access to Therapeutic Trials - Member, 1987-1988

New York State Chapter, American College of Physicians - AIDS Subcommittee of the Health and Public Policy Committee - Member, 1988.

National Institute of Health - Data and Safety Monitoring Board for AIDS Treatment Evaluation Units - Member, 1988-1996

New York State Department of Health AIDS Institute: AIDS Drug Assistance Program - Chairman, Medical Advisory Council 1991-1993.

New York State Department of Health AIDS Institute: HIV Uninsured Care Programs-Member, Steering Committee and Chairman, Clinical Subcommittee - 1993-2001.

EDITORIAL BOARD MEMBER

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EDITORIAL REVIEWER

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Journal American Medical Association
Annals of Internal Medicine
Archives of Internal Medicine
Journal of Infectious Diseases
Clinical Infectious Diseases
The Medical Letter

INVITED LECTURES - NATIONAL OR INTERNATIONAL MEETINGS:

Rahal, J. - Treatment of Fungal Endocarditis Conference on Treatment of Bacterial Endocarditis. American Heart Association National Center, Dallas, Texas - April 28-30, 1980.

Rahal, J. - Staphylococcal Bacteremia and Endocarditis. Symposium on Current Problems in Staphylococcal Infections. 20th Interscience Conference on Antimicrobial Agents and Chemotherapy, New Orleans Louisiana - September 22-24, 1980.

Rahal, J.- Meningitis in Adults. Symposium on Bacterial Meningitis 21st Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago, Illinois - November, 1981.

Rahal, J. - Teaching Staff. International Course on the Evaluation of Antibiotic Resistance Mechanisms: The Methicillin Resistant *Staphylococcus aureus*. Gulbenkian Institute of Science and Rockefeller University, Oeiras, Portugal, July 22, - August 2, 1991.

Rahal, J. - Antimicrobial resistance in Gram-Negative Pathogens: a Global View: Table Ronde Roussel UCLAF, No. 75, Microbial Antibiotic Resistance: Challenge to Science and Chemotherapy. Versailles, France. July 5-6, 1993.

Rahal, J. - Teaching Staff. Salzburg Cornell Seminar in Infectious Diseases. Soros Foundation, Salzburg, Austria. July 13-20, 1996.

Rahal J. - *Acinetobacter*: Fertile soil for the Emergence of Antibiotic Resistance. Infectious Diseases Society of America, Denver, Colorado. November 12, 1998.

Rahal J. Squeezing the antibiotic resistance balloon: Is it inevitable? 41st Interscience Conference Conference Antimicrobial Agents and Chemotherapy, Chicago, Illinois -September, 2001.

Rahal J. Prevention of antibiotic resistance in hospitals. Meet the Experts Session. 41st Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago, Illinois - September, 2001.

Rahal J. Effects of Interferon Alpha-2b on St. Louis Virus Meningoencephalitis. National Institute of Allergy and Infectious Diseases Symposium on West Nile infection. Bethesda, Md. 11/21/02.

Rahal, J. Emerging Resistance in Nosocomial Pathogens - Multidrug-resistant *Acinetobacter* and *Pseudomonas*. International Conference on Emerging Infectious Diseases. Centers for Disease Control and Prevention, Atlanta, GA. 3/1/04.

Rahal J. Combination Therapy for Multiply Resistant *Acinetobacter* and *Pseudomonas*. Update on Serious Gram Negative Bacterial Infections in the I.C.U. University of Pittsburgh, Pittsburgh, PA. 5/8/04

Rahal, J. Epidemiology and Control of Carbapenem Resistance. Interscience Conference on Antimicrobial Agents and Chemotherapy, American Society for Microbiology. Washington, D.C. 10/31/04

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11. Hyams PJ, Smithivas T, Matalon R, Katz L, Simberkoff MS, Rahal JJ Jr. The Use of Gentamicin in Peritoneal Dialysis. II Microbiologic and Clinical Results. J Infect Dis 124:S84, 1971.
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